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APPLICATION NO.	FIL	ING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,865	08/06/2003		Andrew David Carlson	X-11408C	8787
25885	7590	01/24/2005		EXAMINER	
ELI LILLY	AND CC	MPANY	KOSSON, ROSANNE		
	PATENT DIVISION P.O. BOX 6288				PAPER NUMBER
	INDIANAPOLIS, IN 46206-6288			1651	
			DATE MAILED: 01/24/2005	DATE MAILED: 01/24/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Summary	10/635,865	CARLSON ET AL.				
· · · · · · · · · · · · · · · · · · ·	Examiner	Art Unit				
The MAILING DATE of this communication app	Rosanne Kosson	orrespondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	66(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).				
Status		·				
1) Responsive to communication(s) filed on 06 Au	<u>igust 2003</u> .					
2a) This action is FINAL . 2b) ⊠ This						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 13-17 is/are pending in the application 4a) Of the above claim(s) is/are withdray 5) Claim(s) is/are allowed. 6) Claim(s) 13-17 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or	vn from consideration.					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Application ity documents have been received (PCT Rule 17.2(a)).	on No ed in this National Stage				
Attachment(s)	,					
1) Notice of References Cited (PTO-892)	4) Interview Summary					
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/6/03, 12/22/03. 	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	atent Application (PTO-152)				

DETAILED ACTION

The preliminary amendment filed on August 6, 2003 has been received and entered. Claims 1-12 have been canceled, and claims 13-17 have been added.

Accordingly, claims 13-17 are examined on the merits herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a patient have a disease state selected from the group consisting of: thrombotic stroke, deep vein thrombosis, pulmonary embolism, peripheral arterial thrombosis, emboli originating from the heart or peripheral arteries, acute myocardial infarction, disseminated intravascular coagulation, and acute pre- or postcapillary occlusions (the disease recited in claim 16), does not reasonably provide enablement for a method of treating a patient having any disease involving intravascular coagulation. In particular, claim 13 reads on treating a patient having a blood clotting disease in which sufficient blood clots are unable to form, such as hemophilia, thrombocytopenia or a clotting disorder caused by a deficiency of Von Willebrand Factor receptors (Bernard-Soulier syndrome).

Because activated protein C (aPC) is an anticoagulant, one of skill in the art would

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recognize that one should avoid practicing the claimed method on a patient having a blood clotting disorder. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. A holding of non-enablement is therefore required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirahara (US 5,084,273) in view of Mochida Pharmaceutical Co. Ltd. (JP 08-301786, see enclosed English machine translation). Hirahara discloses that activated protein C

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(aPC) may be administered to patients as an anticoagulant to treat intrinsic and extrinsic blood coagulation. Extrinsic blood coagulation is that caused by extravascular tissue factors and phospholipids (see col. 1, lines 9-12, and col. 2, lines 13-15). Thus, aPC may be used to treat blood clots, including blood clots caused by myocardial infarction, transplants or retinal disease. aPC may be formulated as a lyophilized preparation containing a sugar, such as mannitol or sucrose. The lyophilized formulation contains about 1.5 mg of aPC to about 100 mg of mannitol. But Hirahara also discloses that more aPC may be used in the formulation. The total amount of protein in the active ingredient may range from 5 mg to 1 g for an adult of 60 kg (see col. 3, lines 14-36, and col. 4, lines 38-43). Hirahara does not disclose treating blood clots with a specific formulation in which the ratio of aPC to sugar by weight is about 1:5-7.

Mochida discloses lyophilized pharmaceutical preparations of aPC containing 10 mg of aPC and 25 mg of mannitol (see paragraph 20). In the composition of Mochida, the ratio by weight of aPC:mannitol is 1:2.5, while in the composition of Hirahara, the ratio is about 1:67 to 10:1 if 1 g of aPC is used. Thus, in the compositions of Hirahara, the ratio can vary widely.

The manipulation of this ratio is a result-effective parameter which was, at the time of Applicant's invention, routinely optimized by one of ordinary skill in the art of pharmaceutical preparations, as evidenced by the fact that Hirahara provides a wide range of suitable concentrations of aPC in the therapeutic compositions disclosed therein. Thus, the claimed variation in Applicant's method with respect to this parameter clearly would have been obvious at the time of Applicant's invention, the

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determination of a suitable ratio of active ingredient to bulking agent through routine experimentation being well within the capabilities of the artisan of ordinary skill at the time of Applicant's invention. Therefore, a holding of obviousness is required.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson Examiner Art Unit 1651

rk/2005-01-19